REMARKS

Claims 38-41 were pending following the Second Preliminary Amendment dated February 8, 2006. Claims 39 and 40 have been canceled. Claim 38 has been amended. New claims 42 and 43 have been added. Accordingly, upon entry of this amendment, claims 38, 41-43 are pending.

Claim 38 has been amended to recite high stringency conditions for hybridization. Support for this amendment can be found in the specification at page 9, lines 6-8 and page 26, lines 5-7. New claim 42 recites the subject matter deleted from amended claim 38. New claim 43 recites the subject matter deleted from claim 41 (by way of amendment to claim 38). Accordingly, no new matter has been added by way of the claim amendments or new claims. Scope of claimed subject matter is not altered.

Objection to the specification

The specification has been amended to provide the U.S. patent number for parent application Serial No. 09/831,630. Accordingly, this objection to the specification should be withdrawn.

Claim rejections under 35 U.S.C. §§ 101 and 112, first paragraph, utility

Claims 38-41 have been rejected under 35 U.S.C. §§ 101 and 112, first paragraph because the specification allegedly fails to provide a specific and substantial asserted utility or a well established utility. According to the Examiner, "[o]ther than ... SEQ ID NO:8, the specification provides little functional characterization of [the claimed] polynucleotide." Further, the Examiner contends that identifying the polynucleotides as "probes" in the claims "is not a utility specific to the claimed polynucleotide sequence since the claim does not make it clear as to what or which polynucleotide can be probed using the claimed polynucleotide."

These rejections are respectfully traversed. The claimed probes have a specific and substantial utility, which is the identification of β3Gal-T5 genes (specification, page 9, lines 13-27, which states that at the claimed hybridization conditions (or, obviously, higher stringency conditions) the nucleic acids hybridize to β3Gal-T5 and not other family members. βGlcNAc

β3Gal-transferases catalyze linkages found in the glycoproteins of normal epithelium (type 1 chain) and malignant epithelium (type 2 chain) (specification, page 2, lines 1-19). The known β3Gal-transferases (i.e., β3Gal-T1, -T2 and -T3) form type I chain structures (specification, page 2, lines 21-24). Thus, the claimed probes are "of considerable interest to define the gene(s) responsible for formation of these core structures [type II chain structures] in ... malignant epithelium" (specification, page 2, lines 19-21). This utility is substantial and specific because the β3Gal-T5 genes identified with the claimed probe can be used, for example, diagnostically to distinguish normal from neoplastic epithelial cells.

"[A] claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be specific *in the absence of a disclosure of a specific DNA target.*" MPEP § 2107.01. Here, the specification discloses the specific DNA target, i.e., the β3Gal-T5 gene. Thus, the claimed invention has specific utility.

The claimed invention's utility is substantial because, as stated in MPEP § 2107.03:

> "The applicant does not have to prove that a correlation exists between a particular activity and an asserted therapeutic use of a compound as a matter of statistical certainty, nor does he or she have to provide actual evidence of success in treating humans where such as utility is asserted. Instead, as the courts have repeatedly held, all that is required is a *reasonable correlation* between the activity and the asserted use. *Nelson v. Bowler, 626 F.2d 853, 857, 206 USPQ 881, 884 (CCPA 1980).*"

As set forth above, there is reasonable correlation between use of the claimed probes to identify and isolate the β3Gal-T5 gene or segments thereof from individuals, which in turn can be used to characterize the sequence of this gene or segments thereof in malignant epithelial cells.

Accordingly, Applicants submit that the claimed nucleic acid probes of this invention have a specific and substantial utility in accordance with 35 U.S.C. § 101. Applicants therefore respectfully request that the rejections under 35 U.S.C. §§ 101 and 112, first paragraph be withdrawn.

Claim rejections under 35 U.S.C. § 112, first paragraph, enablement

Claims 38-41 have been rejected under 35 U.S.C. § 112, first paragraph for lack of enablement. The Examiner acknowledges that the specification enables an isolated polynucleotide

of less than 10,000 nucleotides wherein the polynucleotide hybridizes to the specified regions of SEQ ID NO:8 under the recited hybridization conditions and wherein the "polynucleotides a full length [sic] polypeptide having [β3Gal-T5] activity." According to the Examiner, the specification does not enable "any such polynucleotide or a complement thereof which simply hybridizes to any 20 contiguous nucleotides of nucleotides 1-115 of SEQ ID NO:8 or nucleotides 428-1011 of SEQ ID NO:8 under stringent conditions of claim 1 and exhibits no encoding activity."

As admitted by the Examiner, the claims "simply" require identification of a polynucleotide or complement thereof that has the property of hybridizing with any 20 contiguous nucleotides of nucleotides 1-115 of SEQ ID NO:8 or nucleotides 428-1011 of SEQ ID NO:8 if subjected to the recited stringency conditions. The specification provides guidance to a person of skill in the art as to how to make and use the probes, setting forth how probes can be made (page 25, line 9 - page 26, line 2) and discussing hybridization conditions, including those considered "stringent" (specification, page 8, line 30 to page 9, line 27). Oligonucleotide hybridization is a well-established concept in molecular biology, dating back over 30 years; it is nothing if not routine. See, Southern, *J. Mol. Biol.,* 1998, 503, 1972. The use of oligonucleotides to bind and screen for nucleic acids has been known in the art for years. Making an oligonucleotide as claimed has been known in the art for over 20 years. *See* specification, page 25. Thus, the claimed probes are enabled. Accordingly, no undue experimentation is required to identify a nucleic acid probe of the instant claims.

The Examiner contends that the claims are not enabled because: "Simply put, above claims encompass variants of polynucleotide sequence of SEQ ID NO:8 which have no function of encoding a functional polypeptide and applicants have not taught those skilled in the art as to where exactly on the polynucleotide sequence of SEQ ID NO:8 specific nucleotides can be modified ... and how to select those modified sequence that show any utility" (Office Action, page 5).

The claims are directed to probes. A "probe" is "a nucleic acid that forms a hybrid structure with a sequence in a target region due to complementarily [sic] of at least one sequence in the probe with a sequence in the target region" (specification, page 10, lines 1-3). The claims are not directed to nucleic acids encoding polypeptides that necessarily possess β3Gal-transferase

activity. The claims are directed to probes and require the skilled artisan to identify: (1) an isolated nucleic acid or complement thereof of less than 10,000 contiguous nucleotides, which (2) hybridizes with a second nucleic acid comprising a specified sequence under (3) certain hybridization conditions. Each of these steps can be routinely performed by one of ordinary skill in the art without undue experimentation. None of these steps require that the probe encode anything. Accordingly, this rejection should be withdrawn.

Claim rejections under 35 U.S.C. § 112, first paragraph, written description

Claims 38-41 have been rejected under 35 U.S.C. § 112, first paragraph because the Examiner contends that the specification "does not contain any disclosure of the function of all DNA sequences that simply hybridize to nucleotides 1-115 or nucleotides 428-1011 of SEQ ID NO:8 under the [recited] stringency conditions."

This rejection is respectfully traversed. The claims are directed to probes. As defined in the specification, a probe is a "nucleic acid that forms a hybrid structure with a sequence in a target region due to complementarily [sic] of at least one sequence in the probe with a sequence in the target region" (specification, page 10, lines 1-3). The claimed probes can be used to identify and/or isolate the β3Gal-T5 gene, or segments thereof, in an individual. Such identification and/or isolation is important for being able to identify mutations or alterations in an individual. Thus, the claimed probes are "of considerable interest to define the gene(s) responsible for formation of these core structures [type II chain structures] in ... malignant epithelium" (specification, page 2, lines 19-21). This utility is substantial and specific because the β3Gal-T5 gene, or segments thereof, identified with the claimed probes can be used, for example, diagnostically to distinguish normal from neoplastic epithelial cells.

Accordingly, the function of the claimed nucleic acids has been sufficiently described and this rejection should be withdrawn.

Claim rejections under 35 U.S.C. § 102(b)

Claims 38, 39 and 41 have been rejected under 35 U.S.C. § 102(b) as anticipated by Szulzewsky et al. (GenBank Accession No. AJ003597, December 4, 1997). According to the Examiner, Szulzewsky discloses a polynucleotide that has a greater than 90% sequence identity to nucleotides 93-115 of SEQ ID NO: 8. The Examiner contends that this nucleotide hybridizes to at least 20 contiguous nucleotides of 93-115 of SEQ ID NO: 3 under the recited stringency conditions.

Szulzewsky discloses a 338 nucleotide sequence in which nucleotides 314-335 have an about 91% identity match to nucleotides 93-115 of the 933 nucleotide sequence represented by SEQ ID NO: 8. Claim 38 has been amended to recite conditions of high stringency, which would exclude the nucleic acid of Szulzewsky. Thus, this rejection should be withdrawn.

Claim rejections for obviousness-type double patenting

Claims 38-41 have been rejected for obviousness-type double patenting over claims 1-10 of U.S. Patent No. 6,800,468. According to the Examiner, claims 38-41 of the instant application and claims 1-10 of the '468 patent are both directed to polynucleotides capable of hybridizing with nucleotides 1-115 and 428-1011 of SEQ ID NO: 8. Applicants will defer responding to this rejection until allowable subject matter has been identified.

Conclusion

Applicants believe that this application is in condition for allowance. Favorable early action is respectfully requested. No new matter has been added.

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Respectfully submitted,

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